

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

TERRESKI MULLINS, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-02952

JOHNSON & JOHNSON, et al.

Defendants.

MEMORANDUM OPINION AND ORDER

On February 14, 2017, I directed the parties to submit simultaneous briefing regarding the contours of what an alternative, feasible design can be under West Virginia law. I asked the parties to cover this issue as broadly as possible, taking into consideration the multiple tort theories available to a plaintiff under West Virginia law. On February 20, 2017, the parties filed their respective briefs [ECF Nos. 1867 & 1868]. On February 21, 2017, the parties filed their respective responses [ECF Nos. 1872 & 1873]. This Order will discuss many of the legal arguments made by the parties in their briefing and at the February 22, 2017, final pretrial conference.

I. Multiple Products Liability Theories

West Virginia law permits plaintiffs to submit multiple products liability theories to the jury. The Supreme Court of Appeals of West Virginia has determined the following:

Product liability actions may be premised on three independent theories—**strict liability, negligence, and warranty**. Each theory contains different elements which plaintiffs must prove in order to recover. No rational reason exists to require plaintiffs in product liability actions to elect which theory to submit to the jury after the evidence has been presented when they may elect to bring suit on one or all of the theories.

Syl. pt. 6, *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603, 605 (W. Va. 1983) (emphasis added). Additionally, the West Virginia Pattern Jury Instructions (“PJI”), § 401, enumerates the three separate theories available to a plaintiff in a products liability case. Further, the PJI establishes different elements for each products liability theory. *See generally* W. Va. P.J.I. § 401, *et seq.* Accordingly, I **FIND** that the plaintiffs in this consolidated trial may present evidence on one or more products liability theories available under West Virginia law, but only the theories sufficiently supported by the evidence admitted at trial may be submitted to the jury.¹

¹ I note that West Virginia law on this point is inconsistent with the Restatement (Third) Torts: Products Liability § 2. *See* Restatement (Third) of Torts: Products Liability § 2 cmt. n (Am. Law Inst. 1998) (“[T]wo or more factually identical defective-design claims or two or more factually identical failure-to-warn claims should not be submitted to the trier of fact in the same case under different doctrinal labels. Regardless of the doctrinal label attached to a particular claim, design and warning claims rest on a risk-utility assessment. To allow two or more factually identical risk-utility claims to go to a jury under different labels, whether ‘strict liability,’ ‘negligence,’ or ‘implied warranty of merchantability,’ would generate confusion and may well result in inconsistent verdicts. In proceedings in which multiple theories are alleged, the Restatement leaves to local law the question of the procedural stage in a tort action at which plaintiff must decide under which theory to pursue the case.”). This inconsistency exists because West Virginia, unlike the Restatement (Third), applies different elements of proof to different products liability theories. Syl. pt. 6, *Ilosky*, 307 S.E.2d at 605; *see also* Restatement (Third) of Torts: Products Liability § 2 cmt. n (“The rules are stated functionally rather than in terms of traditional doctrinal categories. . . . As long as these requisites are met, doctrinal tort categories such as negligence or strict liability may be utilized in bringing the claim.”).

II. Alternative, Feasible Design

I am convinced that an alternative, feasible design must be examined in the context of products—not surgeries or procedures. The Fourth Circuit, in applying Virginia law, has addressed this issue squarely. In *Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999), the Court evaluated an expert’s theory that spinal fixation screws were defective because spinal fusion procedures *with* the screws were not more successful than spinal fusion procedures *without* the screws. The Court ruled as follows:

This testimony, however, did not indicate any design flaw in the Dyna-Lok Device. Rather, it questioned the medical judgment of doctors who use spinal fixation devices in surgery. While such an opinion might be relevant in a malpractice suit against a doctor, it is irrelevant in a suit against the product manufacturer. Thus, the district court did not abuse its discretion in refusing to consider this evidence in a suit against the manufacturer of a spinal fixation device. In summary, we agree with the district court’s conclusion that Talley has failed to come forth with admissible evidence which would permit a jury to conclude that the Dyna-Lok Device was defectively designed.

Talley, 179 F.3d at 162. I am persuaded by the reasoning in *Talley*.²

Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been preformed without the use of the TVT does nothing to

² The Fifth Circuit has reached the same conclusion. *See Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (“Theriot therefore argues that other products that do not use pedicle screws should be considered as alternative designs, such as external neck braces or internal systems that use hooks or wires. Underlying this argument is the assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product. The problem with this argument is that it really takes issue with the choice of treatment made by Theriot’s physician, not with a specific fault of the pedicle screw sold by Danek.”).

inform the jury on the issue of an alternative, feasible *design* for the TVT. Instead, alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence (“SUI”); other surgeries or procedures do not inform the jury on *how* the TVT’s design could have feasibly been made safer to eliminate the risks that caused the plaintiffs’ injuries. *See Talley*, 179 F.3d at 162; W. Va. P.J.I. § 411.

The plaintiffs have also argued that polypropylene sutures should be considered an alternative, feasible design for the TVT. The basis of their argument is that the TVT device is essentially made up of woven-together sutures, forming a mid-urethral sling. I am not persuaded by this argument. In fact, Ethicon has made the exact argument in order to invoke relevant federal preemption doctrines, and I have previously found that Ethicon’s argument lacks merit:

Ethicon’s argument ignores the fact that the Prolene suture and the TVT are two entirely different medical devices that went through different FDA processes. Although Ethicon represents that the products are primarily composed of the same material, it does not automatically follow that the material is safe in both devices. The Prolene suture is a nonabsorbable surgical suture; the TVT is a form of transvaginal mesh. The Prolene suture consists of a single filament of polypropylene; the TVT is a mesh woven from knitted Prolene filaments. The average Prolene suture is a few inches long; the TVT measures one-half inches by sixteen inches, and contains many times the amount of polypropylene material. The Prolene suture is not intended to adhere to human tissue; the TVT is designed to adhere to human tissue. The Prolene suture is

designed to be easily pulled out of the body; the TVT cannot be removed without invasive surgery.

Huskey v. Ethicon, Inc., 29 F. Supp. 3d 736, 747 (S.D. W. Va. 2014) (quoting *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 757–59 (S.D. W. Va. 2014)). Thus, I have previously ruled that a polypropylene suture and the TVT device are entirely different products, performing different functions. Accordingly, I **FIND** that a polypropylene suture is not an alternative, feasible design for the TVT device as a matter of law.

I further **FIND** that the plaintiffs must provide evidence of an alternative, feasible design for the *product* at issue—in this case, the TVT. Once the court determines that the plaintiffs have provided sufficient evidence to identify a comparable product or design concept, whether the *design features* of the comparable product or the *design concept* existing at the time of the TVT's manufacture is an alternative, feasible design for the TVT is a factual question left to the jury.

III. Negligence

The defendants argue that an alternative, feasible design is required for proving the plaintiffs' cases under *both* strict liability and negligence. The defendants' primary argument is that because both theories apply the risk/utility test, both must require evidence of an alternative, feasible design. As I have already pointed out, the West Virginia Supreme Court has held that negligence and strict liability claims have different elements. Syl. pt. 6, *Ilosky*, 307 S.E.2d at 605. Moreover, the PJI even separates the products liability instructions based on negligence, strict liability, and

breach of warranty theories, establishing different elements of proof for each. Sections 424 and 425 of the PJI state the applicable standards for negligence in a products liability case, and absent from these instructions is any element of proof regarding an alternative, feasible design. *See* W. Va. P.J.I. §§ 424, 425. Unlike in strict liability, where the defective condition of the product is the principal basis of liability, negligence focuses on the *conduct* of the manufacturer. *See* Syl. pt. 3, *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 667 (W. Va. 1979) (“The cause of action covered by the term ‘strict liability in tort’ is designed to relieve the plaintiff from proving that the manufacturer was negligent in some particular fashion during the manufacturing process and to permit proof of the defective condition of the product as the principal basis of liability.”); *see also* 63 Am. Jur. 2d *Products Liability* § 519 (“Strict liability looks at the product itself and determines if it is defective, whereas negligence looks at the act of the manufacturer and the court determines if the manufacturer exercised ordinary care in design and production.”) Certainly, the existence of an alternative, feasible design is relevant to the manufacturer’s conduct, but a requirement to establish an alternative, feasible design is simply not among the requisite elements under a negligence products liability theory.

Accordingly, I **FIND** that under West Virginia law, the plaintiffs are *not* required to provide evidence of an alternative, feasible design under a negligence theory of products liability.

IV. Malfunction Theory

The malfunction theory is available to the plaintiffs in this case. West Virginia case law and the PJI allow a plaintiff to prove his or her design defect strict liability case with circumstantial evidence. Specifically, the West Virginia Supreme Court has determined the following:

Circumstantial evidence may be sufficient to make a *prima facie* case in a strict liability action, even though the precise nature of the defect cannot be identified, so long as the evidence shows that a malfunction in the product occurred that would not ordinarily happen in the absence of a defect. Moreover, the plaintiff must show there was neither abnormal use of the product nor a reasonable secondary cause for the malfunction.

Syl. pt. 3, *Anderson v. Chrysler Corp.* 403 S.E.2d 189, 190 (W. Va. 1991); *see also Bennett v. ASCO Servs., Inc.*, 621 S.E.2d 710, 717 (W. Va. 2005) (referring to *Anderson's* “malfunction theory”). Additionally, § 407 of the PJI provides an instruction on the malfunction theory under a strict liability framework, which is nearly identical to § 3 of the Restatement (Third) of Torts: Products Liability.

I am not persuaded by the defendants’ argument that the plaintiffs are not permitted to advance a malfunction theory simply because they have identified alleged specific design flaws in the TVT. From the cases I have reviewed, nothing indicates that a plaintiff is barred from advancing the malfunction theory just because the plaintiff also has identified a possible design flaw. *See Bennett*, 621 S.E.2d at 718 (“We must therefore consider whether the Bennetts offered sufficient evidence—**circumstantial or otherwise**—to create a triable issue of fact regarding

whether the alarm system components were not reasonably safe for their intended use.” (emphasis added)). Instead, allowing the plaintiffs to advance the malfunction theory alongside a more traditional strict liability theory (that is, one where direct evidence of a design flaw is offered along with an alternative, feasible design) is consistent with *Ilosky*, which allows multiple theories to go to the jury. Syl. pt. 6, *Ilosky*, 307 S.E.2d at 605. Accordingly, I **FIND** that the plaintiffs may proceed under the malfunction theory of strict products liability.

The parties have also raised the issue of whether an alternative, feasible design is a required element of proof under the malfunction theory. I have found no such requirement under West Virginia law. First, neither *Anderson* nor *Bennett* requires evidence of an alternative, feasible design. *See generally Anderson*, 403 S.E.2d at 190; *Bennett*, 621 S.E.2d at 712–13. Second, § 407 of the PJI—the instruction applicable to the malfunction theory—does not mention an alternative, feasible design in its enumerated elements of proof. Finally, § 3 of the Restatement (Third) offers highly persuasive commentary, stating that an alternative, feasible design is not a required element of proof under the malfunction theory. Restatement (Third) of Torts: Products Liability § 3 reporters’ note 1 (concluding that under § 3, “[t]he plaintiff need not prove that . . . a reasonable alternative design could have been adopted”); *see also* Aaron D. Twerski & James A. Henderson Jr., *Manufacturers’ Liability for Defective Product Designs: The Triumph of Risk-Utility*, 74 Brook. L. Rev. 1061, 1108 (2009) (“Indeed, section 3 of the Products Liability Restatement

enthusiastically supports the principle that there is no need to prove a reasonable alternative design when a product fails to perform its manifestly intended function.”).

The Supreme Court of Appeals of West Virginia appears to have essentially adopted the elements of proof discussed in § 3 of the Restatement (Third). *See* W. Va. P.J.I. § 407; syl. pt. 3, *Anderson*, 403 S.E.2d at 190. Additionally, the applicable case law and PJI sections do not indicate that an alternative, feasible design is a required element under a malfunction theory. Accordingly, I **FIND** that the plaintiffs in this case are not required to produce evidence of an alternative, feasible design to establish a prima facie case under the malfunction theory adopted in *Anderson*.³

V. Conclusion

For the reasons discussed above, the court **ORDERS** as follows:

- (1) The plaintiffs in this consolidated trial may present evidence of one or more products liability theories available under West Virginia

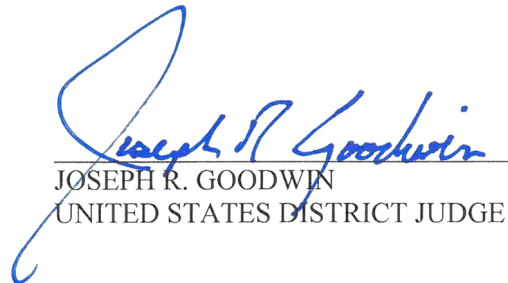
³ It appears at first blush that a plaintiff who can readily identify a purported design defect has a more difficult journey to proving her direct evidence strict liability case than a plaintiff advancing a circumstantial evidence strict liability case. I can only reconcile these differing elements by taking stock of the different, but considerable, burden a plaintiff must actually overcome under the malfunction theory. In *Bennett*, the West Virginia Supreme Court held that “while a defect in a product cannot be presumed solely from the fact that an accident occurred, proof that a product malfunctioned—that is, failed to function as it was intended and typically would in normal usage—is circumstantial proof of its defective condition.” *Bennett*, 621 S.E.2d at 717; *see also* Restatement (Third) of Torts: Products Liability § 3 cmt. b (“Section 3 claims are limited to situations in which a product fails to perform its manifestly intended function, thus supporting the conclusion that a defect of some kind is the most probable explanation.”); *id.* at reporters’ note 2 (“The inference of defect may not be drawn, however, from the mere fact of a product-related accident.”). Thus, under the malfunction theory, the plaintiffs in this consolidated trial must first meet the burden of showing that the TVT device failed to perform its intended function, which is the treatment of SUI. Accordingly, both the direct evidence and the circumstantial evidence theories of strict products liability under West Virginia law pose their own individual challenges.

law, but only the theories sufficiently supported by the evidence admitted at trial may be submitted to the jury.

- (2) Evidence that an alternative surgical procedure should have been used in place of the TVT device is not an alternative, feasible design as a matter of law.
- (3) A polypropylene suture is not an alternative, feasible design for the TVT device as a matter of law.
- (4) Once the court determines that the plaintiffs have provided sufficient evidence to identify a comparable product or design concept, whether the design features of the comparable product or the design concept existing at the time of the TVT's manufacture is an alternative, feasible design for the TVT is a factual question left to the jury.
- (5) Under West Virginia law, the plaintiffs are not required to provide evidence of an alternative, feasible design under a negligence theory of products liability.
- (6) The plaintiffs may proceed under the malfunction theory of strict products liability.
- (7) Under West Virginia law, the plaintiffs are not required to produce evidence of an alternative, feasible design under the malfunction theory.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 23, 2017



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE